



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/686,997	10/12/00	DE LACHARRIERE	0 196726US0

022850 HM12/0730
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EXAMINER	
WILLIS, M	
ART UNIT	PAPER NUMBER
1619	4

DATE MAILED: 07/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/686,997	DE LACHARRIERE ET AL.	
	Examiner	Art Unit	
	Michael A. Willis	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1</u> | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Claims 1-35 are pending. Claims 1-11 are drawn to a method of regulating the pigmentation of skin and/or superficial body growths. Claims 12-22 are drawn to a method of de-pigmenting and/or bleaching for the skin and/or to improving the homogeneity of the color of the skin. Claims 23-33 are drawn to a method of pro-pigmenting superficial body growths. Claims 34-35 are drawn to compositions.

Specification

1. The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper (see pages 8, 9, and 13). Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

Information Disclosure Statement

2. The information disclosure statement filed 12 October 2000 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that

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portion which caused it to be listed. A copy of EP 0853472A1 is missing. The reference has not been considered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 1-2, 4-7, 9-13, 15-18, 20-24, 26-29, 31-34 are rejected due to the term "derivative". The term is not defined by the claims, the specification does not provide a standard for ascertaining which compounds are derivatives, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

6. Claims 4, 15, and 26 are rejected due to the phrase "(or adiol)". The meaning of the phrase is unclear.

7. Claims 34-35 are rejected due to the phrase "in particular". The phrase is a narrower statement within a broader statement in the same claim. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation in the same claim is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is

followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

8. Claim 34 is rejected for being confusing due to the phrase "arbutin derivatives thereof". The parent compound of the arbutin derivatives is unclear.
9. Any remaining claims are rejected for depending from an indefinite base claim.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Hadley et al ("Hormonal control of melanogenesis," *Pigm. and Pigm. Disord.*, ed. Norman Levine, 1993, pp.95-114). Hadley teaches that estrogens administered topically produce hyperpigmentation of the skin (see page 105, last paragraph).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hadley et al ("Hormonal control of melanogenesis," *Pigm. and Pigm. Disord.*, ed. Norman Levine, 1993, pp.95-114) in view of Breton et al (US Pat. 5,989,568).

14. Hadley teaches that estrogens administered topically produce hyperpigmentation of the skin (see p. 105, last paragraph). Hadley also teaches that androgens and estrogens exhibit site-specific stimulatory or inhibitory actions on pigmentation (see page 106, fifth paragraph) and that melanin production is increased by androgens in a general manner (see p. 106, third paragraph). Additionally, Hadley teaches that UV light plays an important role in the acquired skin pigmentation in humans in that exposure induces an increase of melanocytes in exposed human skin as well as in shielded areas (see p. 102, last paragraph through p. 103, first paragraph). The reference lacks formulations of steroidal hormones as topical compositions.

15. Breton teaches cosmetic or dermatological skin care compositions comprising S-DHEA. The compositions are useful for treating signs of endogenous or exogenous aging. These conditions are defined to include pigmentation marks, especially on areas exposed to sunlight (see col. 1, lines 5-25). The compositions also include hormones other than S-DHEA, including androstenedione (see col. 3, lines 40-46). Breton teaches

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the use of conventional additives such as sunscreens, plant oils, and retinoids (see col. 2, line 55 through col. 3, line 46).


16. It would have been obvious to one of ordinary skill at the time the invention was made to have modified the teachings of Hadley by incorporation of steroidal hormones into topical compositions as taught by Breton in order to benefit from the topical use of the compositions.

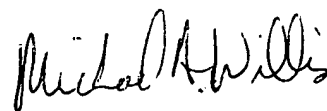
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael A. Willis whose telephone number is (703) 305-1679. The examiner can normally be reached on Mon. to Fri. from 9 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on (703) 308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2742 for regular communications and (703) 308-2742 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.


Michael Hartley
Primary Examiner


Michael A. Willis, Ph.D.
Patent Examiner
Art Unit 1619

July 30, 2001